**REMARKS**

Claims 1-18 and 21-54 are pending in the instant application. Claims 1-18 and 21-24 have been rejected. Claims 1, 14, 21, 33, 38 and 50 have been amended. Claim 8, 27 and 41 have been canceled. Support for these amendments is provided in the specification at page 3, lines 19 through 26, page 11, lines 27-29 and in claims 8 and 21, now canceled. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Notice to Comply with Requirements for Patent Applications containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures**

The Examiner has objected to the application as failing to comply with 37 C.F.R. 1.821(d). In particular, the Examiner suggests that sequences disclosed on pages 9-10 are not identified by sequence identifiers.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the specification at page 9 to include the appropriate sequence identifier, namely SEQ ID NO:1, as set forth in the Sequence Listing, prior to the teaching

of this sequence. No new matter is added by these amendments and entry is respectfully requested.

Withdrawal of this objection is respectfully requested in light of these amendments.

**II. Priority**

Applicants have amended the specification to include a claim to priority in accordance with the executed Declaration filed July 16, 2002.

**III. Objection to Drawing**

Drawing 1 has been objected to as not being labeled as Figure 1. A proposed drawing correction is provided herewith wherein this drawing contains the label of Figure 1. No new matter is added by this amendment. Withdrawal of this objection is respectfully requested in light of this proposed amendment.

**IV. Objection to Claim 41**

Claim 41 has been objected to as being in improper dependent form for failing to further limit the subject mater of the previous claim. Accordingly, Applicants have canceled claim 41 thus mooting this objection. Withdrawal of this objection is therefore respectfully requested.

**V. Rejection of Claims 14, 33, 38 and 41 under 35 U.S.C. § 112, second paragraph**

Claims 14, 33, 38 and 41 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggests that the phrase "two amino acids substitutents in the H-chain gene respectively" is indefinite. Further, with respect to claim 41, the Examiner suggests that the metes and bounds of the limitation "further comprises a gene sequence encoding a secretion signal" is unclear.

Accordingly, in an earnest effort to advance the prosecution, Applicants have amended claims 14, 33 and 38 to clarify that there are two amino acid substitutions in the H-chain gene, respectively. Support for this amendment can be found in the specification at page 11, lines 27-29. Further, Applicants have canceled claim 41.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph is therefore respectfully requested.

**VI. Rejection of Claims 1-18 and 21-54 under 35 U.S.C. § 112, first paragraph**

Claims 1-18 and 21-54 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be enabling for a composition for protection of a fish against viral haemorrhagic septicaemie virus (VHSV) comprising a non-infectious DNA nucleic acid construct encoding the single chain antibody 3F1H10 that recognizes VHSV, the DNA sequence for the antibody listed on pages 9-10 of the specification and which comprises substitutions of asparagine 35 with threonine and lysine 64 with threonine and is linked at the 5' end to the secretion signal of transforming growth factor beta, and which sequence is operably linked to the CMV promoter and a polyA tail for protecting fish against VHSV infection. The Examiner also acknowledges the specification to be enabling for vaccines comprising such compositions and methods of providing prophylactic treatment of fish against VHSV by administration of these compositions by injection into the epaxial muscle below the dorsal fin which results in transformation of the cells at the injection site to produce secreted 3F1H10 antibodies. However, the Examiner suggests that the specification does not reasonably provide enablement for any nucleic acid construct encoding any

antibody, any secretion sequence, any promoter sequence, any form of administration, any form of composition, treatment of any animal or any form of treatment to any agent.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's characterization of the claims. Contrary to the Examiner's suggestion, the pending claims are not drawn to any nucleic acid construct encoding any antibody, but rather are drawn to a non-infectious nucleic acid construct encoding a recombinant antibody against a disease-causing agent. Further, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to clarify that the non-infectious nucleic acid construct, upon administration to the animal, encodes a recombinant antibody against a disease causing agent and that the non-infectious nucleic acid construct further comprises a gene sequence encoding a secretion signal peptide. Support for these amendments is provided in the specification at page 3, lines 19 through 26 and in claims 8 and 21, now canceled.

Applicants also respectfully disagree with the Examiner=s suggestion that aspects considered broad in the instant claims are not reasonably fleshed out so that one of ordinary skill in the art at the time of the invention would be able to practice

the instant invention. A detailed list of possible pathogens to which a non-infectious nucleic acid construct of the presence invention can be prepared is set forth at pages 5-6 of the instant application. Further, exemplary signal sequences for secretion are taught at page 6, line 26 through page 7, line 9. In addition, various routes of administration and forms of the compositions for delivery are taught at page 7, lines 20-30.

Applicants are also providing herewith a Declaration by inventor Lorensen demonstrating efficacy of a nucleic acid construct prepared and administered in accordance with the teachings of the instant application in mice. This Declaration clearly establishes that the skilled artisan in accordance with teachings of the instant application can make and use nucleic acid constructs other than the exemplary DNA nucleic acid construct encoding the single chain antibody 3F1H10 that recognizes VHSV in fish.

MPEP § 2164.08 and the holding of the courts are quite clear; claims are not to be rejected as broader than the enabling disclosure under 35 U.S.C. ' 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the

specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801,806, 166 USPQ 85,88 (CCPA 1970). Thus, the general methods by which compositions of the present invention can be administered, promoter signal sequences useful in the constructs, various routes of administration and formulations of compositions to be administered, which are well known and therefore obvious factors, need not be recited specifically in the claims.

Also made clear in MPEP ' 2164.08 and by the courts is that one does look to the claims but to the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.* 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). Suggestions by the Examiner to include the specific methodologies used to demonstrate efficacy of the exemplary DNA nucleic acid construct encoding the single chain antibody 3F1H10 that recognizes VHSV in fish are clearly related to practice of the claimed invention and thus need not be specifically outlined in the claims since they are clearly taught in the specification.

Finally, the court in *In re Goffe* made clear in their holding that

> "[t]o demand that the first to disclose shall limit his claims to what he has found will work or to material which meet the guidelines specification for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts." (542 F.2d 564, 567; 191 USPQ 429, 431 (CCPA 1976); MPEP 2164.08)

Thus, the Examiner's suggestion that to meet the enablement requirements the claims must be limited to the specific exemplary nucleic acid construct demonstrated to be effective in fish, when broader applications are taught in the specification and well known to those skilled in the art, is clearly improper in light of teachings of the MPEP, holdings of multiple courts and the constitutional purpose for the patent statute.

Withdrawal of this rejection under 35 U.S.C. ' 112, first paragraph is therefore respectfully requested in light of the amendments to the claims and the above arguments.

**VII. Rejection of Claims 1-7, 9, 12-13, 16-18, 21-27, 31-32, 35-37 and 44-54 under 35 U.S.C. § 102(b)**

Claims 1-7, 9, 12-13, 16-18, 21-27, 35-37 and 44-54 have been rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/37234. Applicants respectfully traverse this rejection.

WO 96/37234 discloses a method for gene therapy using a recombinant gene encoding an antibody that is selectively

specific for an intracellular antigen associated with a disease. Thus, the antibody in WO 96/37234, unlike the antibody in the present invention, is not secreted from the cells.

Accordingly, in an earnest effort to clearly distinguish the present invention from the prior art teachings of WO 96/37234, Applicants have amended the claims to clarify that the non-infectious nucleic acid construct also comprises a gene sequence encoding a secretion signal peptide. Support for this amendment is provided in claims 8 and 27, now canceled.

Since WO 96/37234 does not teach a recombinant gene encoding an antibody and a secretion signal peptide, this reference cannot anticipate the claims as amended. See MPEP § 2131.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

**VIII. Rejection of Claims 1, 8, 15, 21, 27 and 34 under 35 U.S.C. § 102(b)**

Claims 1, 8, 15, 21, 27 and 34 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,543,144. Applicants respectfully traverse this rejection.

U.S. Patent 5,543,144 discloses production of single chain antibodies which are then collected and administered to the

patient. In contrast, in the present invention the antibodies are expressed within the animal to which the construct is administered.

Accordingly, in an earnest effort to advance the prosecution and to clearly distinguish the present invention from prior art teachings such as U.S. Patent 5,543,144, Applicants have amended the claims to clarify that the non-infectious nucleic acid construct, upon administration to the animal, encodes a recombinant antibody. Support for this amendment is provided at page 3, lines 19 through 26, of the instant application.

Since U.S. Patent 5,543,144 does not teach a non-infectious nucleic acid construct, which upon administration to the animal, encodes a recombinant antibody, this reference cannot anticipate the claims as amended. See MPEP § 2131.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

**IX. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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